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REMARKS/ARGUMENTS

With this amendment, claims 37-40 and 44-51 are pending. Claims 1-36 and 41-43 are cancelled without prejudice. For convenience, the Examiner's rejections are addressed in the order presented in a May 26, 2006, Office Action.

I. Status of the claims

Claims 37, 38, and 49-51 are amended to recite a *N. meningitidis* α-2,3-sialyltransferase and a *N. meningitidis* CMP-Neu5Ac synthetase. Support for these amendments is found throughout the specification, for example, at page 39, lines 1-4 and page 39, line 31 through page 40, line 16. These amendments add no new matter.

II. Rejections under 35 U.S.C. §112, second paragraph

Claims 49-51 are rejected for alleged indefiniteness. According to the Office Action, use of the phrases "first, second, third or forth primer" is unclear. In order to expedite prosecution, Claims 49-51 are amended to remove the phrases "first, second, third or forth primer". In view of these amendments, withdrawal of the rejections for alleged indefiniteness is respectfully requested.

III. Rejections under 35 U.S.C. §112, first paragraph, enablement

Claims 37-51 are rejected under 35 U.S.C. §112 first paragraph, because the specification allegedly does not enable the full scope of the claims. The Office Action does indicate that the specification provides enablement of a fusion protein comprising a *Neisseria meningitidis* (*N. meningitides*) α-2,3-sialyltransferase and a *N. meningitidis* CMP-Neu5Ac synthetase. To the extent the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

In order to expedite prosecution, claims 37, 38, and 49-51 are amended to recite a *N. meningitidis* α-2,3-sialyltransferase and a *N. meningitidis* CMP-Neu5Ac synthetase. It is Applicant's understanding that this amendment puts the claims in condition for allowance.

The Federal Circuit has recently provided guidance on the amount and type of disclosure required to enable a known amino acid or nucleic acid sequence recited in a claim. The court ruled that where sequences had been disclosed previously in professional journals and were, thus, readily accessible to the public, enablement did not require incorporation by reference, much less recitation of the actual sequences in the application. *See, e.g., Falkner v. Inglis*, 79 USPQ2d 1001, 1006 (Fed. Cir. 2006). Both the *N. meningitidis* α-2,3-sialyltransferase and a *N. meningitidis* CMP-Neu5Ac synthetase nucleic acid sequences were known at the time of filing. Therefore, recitation of known sequences is **not** required to meet the enablement standard put forth by the Federal Circuit and, thus, this rejection should be withdrawn.

In view of the above amendments and remarks, withdrawal of the rejections for alleged lack of enablement is respectfully requested.

IV. Rejections under 35 U.S.C. §112, first paragraph, written description

Claims 37-51 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. According to the Office Action, the specification does not provide adequate description of the genus of the claimed nucleic acids. The Office Action alleges that those of skill would not recognize that the inventors had possession of the claimed invention at the time of filing. To the extent the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

First the amended claims are now directed to a fusion protein comprising an *N. meningitides* α-2,3-sialyltransferase and an *N. meningitidis* CMP-Neu5Ac synthetase. Applicants remind the Examiner that the description of this fusion was addressed in a response and declaration filed on March 2, 2004. The written description rejection was then withdrawn with the Office Action mailed May 26, 2005.

Applicants also respectfully assert that, because the sequences of both the *N. meningitides* α-2,3-sialyltransferase and the *N. meningitidis* CMP-Neu5Ac synthetase were known at the time of filing, the specification as filed meets the written description requirement. The Federal Circuit Court of Appeals has made it clear that there is no *per se* rule regarding inclusion of sequence information in a patent application to support description of a nucleic acid

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sequence, and by analogy an amino acid sequence. "When the prior art includes the nucleotide information, precedent does not set a per se rule that the information must be determined afresh." *Capon v. Eshar*, 76 USPQ2d 1078, 1084-5 (Fed. Cir. 2005). In fact, the Federal Circuit has recently ruled that even incorporation by reference of known sequences is not required for the written description requirement. "Accordingly we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences. . . , satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted)of such genes and sequences." *Falkner v. Inglis*, 79 USPQ2d 1001, 1008 (Fed. Cir. 2006). Thus, the application meets the written description requirement for the claimed nucleic acid sequences.

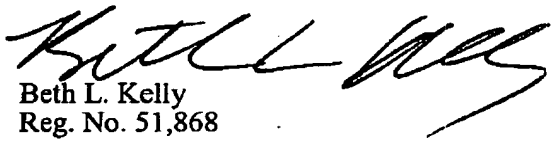
In view of the above amendments and remarks, withdrawal of the rejections for alleged lack of written description is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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